510(k) SUMMARY

JUL 16 2012

Implanet S.A.'s Calypso System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Implanet S.A.
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Contact Person: Franck Rigal, Director of Quality and Regulatory Affairs

Date Prepared: July 12, 2012

Name of Device

Calypso System

Common or Usual Name

Spinal fixation device

Classification Name

888.3070 – Pedicle Screw Spinal System

888.3050 – Spinal interlaminal fixation orthosis

Predicate Devices

Aesculap Implant Systems, Inc.'s S4 Spinal System (K100623)

Medtronic Sofamor Danek USA, Inc.'s CD HORIZON Spinal System (K113174)

Intended Use / Indications for Use

The Implanet Calypso System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion of the thoracic, lumbar and/or sacral spine. The Implanet Calypso System is intended for posterior, non-cervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, spinal deformities (i.e., scoliosis, kyphosis and/or lordosis), tumor, pseudoarthrosis, or revision of a failed fusion attempt.

Technological Characteristics

The Calypso System is a posterior instrumentation system consisting of monoaxial and polyaxial pedicle screws, union rods, transverse connectors, and hooks. The implants in the system are composed of Ti6Al4V titanium alloy described by ISO 5832-3.

Performance Data

In support of this 510(k) Premarket Notification, Implanet S.A. has conducted bench testing to demonstrate that the Calypso System provides adequate mechanical strength for its intended use. All bench testing confirmed that the product met the necessary specifications. In addition, the biocompatibility of the device has been confirmed in accordance with ISO-10993, and the company has conducted sterilization and shelf life validation in accordance with recognized industry standards. A list of the tests performed to support substantial equivalence is provided below:

- Static axial gripping capacity, static flexion/extension bending, static axial torque gripping capacity- ASTM F1798
- Static compression bending – ASTM F1717
- Static torsion – ASTM F1717
- Dynamic compression bending – ASTM F1717
- Cytotoxicity – ISO 10993
- Acute systemic toxicity – ISO 10993
- Shelf life – ASTM 1980
- Implant sterilization validation – ISO 11137
- Instrument cleaning and sterilization validation – ISO 17665

Substantial Equivalence

The Calypso System is very similar to the Aesculap Implant Systems, Inc.'s S4 Spinal System and Medtronic Sofamor Danek USA, Inc.'s CD HORIZON Spinal System. The Calypso System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Calypso System and its predicate devices raise no new issues of safety or effectiveness. Performance data, including mechanical testing in static compression bending, static torsion, and dynamic compression bending, as well as biocompatibility and sterility testing, demonstrate that the minor differences between the Calypso System and the predicates do not adversely impact its performance. Thus, the Calypso System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Hogan Lovells US, LLP
% Ms. Janice Hogan
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

JUL 16 2012

Re: K120564
Trade/Device Name: Calypso System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, MNH, KWP
Dated: June 21, 2012
Received: June 21, 2012

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

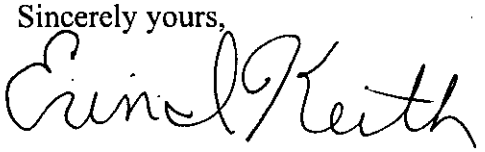
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K120564

Device Name: Calypso System

Indications for Use:

The Implanet Calypso System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion of the thoracic, lumbar and/or sacral spine. The Implanet Calypso System is intended for posterior, non-cervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, spinal deformities (i.e., scoliosis, kyphosis and/or lordosis), tumor, pseudoarthrosis, or revision of a failed fusion attempt.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

10(k) Number K120564